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| 09/462,341 | 04/13/2000 | ERIC GORDON MAHERS | 602-1466 | 4968 |
| 23644 | 7590 | 01/12/2005 | EXAMINER | |
| BARNES & THORNBURG | | | DASTOURI, MEHRDAD | |
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2623

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,341

Applicant(s)

MAHERS ET AL.

Examiner

Mehrdad Dastouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 6-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed July 2, 2004, have been entered and made of record.

Response to Arguments

2. Applicant's remarks filed July 2, 2004, have been fully considered but they are not persuasive.

Applicants argue in essence that prior art of record ((Domanik) does not disclose any numeral or letter code printed on the discs in addition to the bar code.

The Examiner disagrees and indicates that claim language recites "the machine readable information comprises **a code of one or more letters and one or more numerals**". Domanik clearly disclose this limitation as explained in Column 2, Lines 19-22. The machine readable code provides identity (i.e., a code of one or more letters) and concentration information (i.e., a code of one or more numerals) for the antibiotic. Claim language does not recite "the machine readable information comprises one or more letters and one or more numerals". Neither claim language recites "the machine readable information comprises a combination of machine readable code and one or more letters and one or more numerals".

It is further submitted that the device also includes orientation means for enabling an image analyzer to determine an optimal reading direction of the readable information as disclosed in Column 3, Lines 57-67, Column 4, Lines 1-25. The tooth that extends from the outer ring 30 to the inner ring 20 creates a solid line that serves as an index

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mark or an orientation marker for the combination of seven possible tooth design to enable the image analyzer to determine an optimal reading direction of the readable information.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 6-8 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Domanik (U.S. 5,798,514).

Regarding Claim 1, Domanik disclose a carrier device for use in an antibiotic susceptibility test ("AST"), the device releasably carrying an antibiotic related to the test (Figures 1-3; Column 1, Lines 10-16; Column 4, Lines 28-39), and bearing machine readable information concerning the antibiotic (Column 2, Lines 19-22), wherein the device also includes orientation means for enabling an image analyzer to determine an optimal reading direction of the readable information (Figures 1 and 2, teeth 40), the device is an AST disk (Figure 3, Component 60), the machine readable information comprises a code of one or more letters and one or more numerals (Column 2, Lines 19-22. The code provides identity (one or more letters) and concentration information (one or more numerals) for the antibiotic.) and wherein the orientation means comprises

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means other than said code (Figures 1 and 2. Teeth 40 (orientation means) define radial positions at which the information code is encoded.).

Regarding Claim 3, Domanik further discloses a device according to Claim 1, in which the orientation means is separate from said machine readable information (Figures 1 and 2. Teeth 40 arrangements are the orientation means comprising a tooth that serves as an index mark. The teeth arrangements or orientation means are different from the machine readable code.).

Regarding Claim 6, Domanik further discloses a device according to Claim 1, in which the orientation means comprises an arrangement of information presented on the device surface, in addition to the code (Figures 1 and 2; Column 2, Lines 9-28; Column 3, Lines 58-67, Column 4, Lines 1-25).

Regarding Claim 7, Domanik further discloses a device according to Claim 1, in which said orientation means comprises linearly-arranged information (Figures 1 and 2. The arrangement of teeth 40 which are linearly extended every 45° (not circumferentially).).

Regarding Claim 8, Domanik further discloses a device according to Claim 7, wherein said linearly-arranged information is parallel to the optimal reading direction of the readable information (Column 2, Lines 13-23).

Regarding Claim 11, Domanik further discloses a device according to Claim 1, in which said code identifies said substance and/or its concentration (Column 2, Lines 19-22).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domanik (U.S. 5,798,514).

Regarding Claim 9, Domanik does not disclose a device according to Claim 7, wherein said linearly-arranged information is a printed line or lines, printed below or above code.

utilizing a printed line or lines, printed below or above a code as a linearly-arranged information for enabling an image analyzer to determine an optimal reading direction of the readable information is well known in the art (Official Notice).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Domanik's invention to include printed lines, printed below or above a code as a linearly-arranged information for enabling an image analyzer to determine an optimal reading direction of the readable information because it is an standard fundamental procedure routinely implemented in image processing for identifying the direction of randomly oriented patterns or characters.

Regarding Claim 10, arguments analogous to those presented for Claim 9 are applicable to Claim 10. An underline is a printed line below the code.

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7. Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domanik (U.S. 5,798,514) in view of Perry (U.S. 3,757,299).

Regarding Claim 12, Domanik discloses an image analysis system for interpreting AST plates (Petri dish), each of which holds a plurality of devices each in accordance with Claim 1 (Column 3, Lines 6-11, machine code reader), the system comprising:

support means for supporting an AST plate (Even though it is not shown in Figure 3, Petri dish is intrinsically supported by a supporting means.);

image capturing means for imaging a plate supported by said support means (Column 4, Lines 54-58); and

electronic information processing means, linked to said image capturing means, programmed or trained to locate an AST disk on said plate from among the plurality of AST disks (Column 4, Lines 58-66),

identify orientation means on the located disks, and rotate the perceived image of the located disks as required so that the perceived image of a multi-character code printed on the device is brought into alignment with a proper reading direction for the code, and read the code (Column 4, Lines 62-67, Column 5, Lines 1-45). Arguments analogous to those presented for Claims 9 and 10 concerning optimal reading directions are applicable to Claim 12.

Domanik does not explicitly disclose a camera as the image capturing device.

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Perry discloses an apparatus for measuring zones of inhibition in a biological assay comprising a camera for imaging a Petri dish (Figures 3, 5 and 18, Cameras 21, 42, 152 and 160).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Domanik's invention according to the teachings of Perry to utilize a camera for capturing image because it is an standard fundamental image capturing device routinely used in image processing.

8. Regarding Claim 13, Domanik further discloses an image analysis system according to Claim 12, which additionally determines the size of the zone of inhibition, if any, surrounding an AST disk (Column 1, Lines 17-30). Furthermore, Perry also discloses determining the size of the zone of inhibition, if any, surrounding an AST disk (Figures 1 and 2; Column 4, Lines 40-68, Column 3, Lines 1-12).

Regarding Claim 14, Domanik further discloses an image analysis system according to Claim 13, wherein the electronic information processing means includes or is linked to an expert system comprising a database of AST characteristics of known micro-organisms (Column 4, Lines 4-60).

Regarding Claim 15, Perry further discloses an image analysis system according to Claim 13 including display means for displaying an AST disk image (Figure 3, display 34).

Regarding Claim 16, Perry further discloses an image analysis system according to Claim 13 wherein the diameter of the zone of inhibition is determined (Column 2, Lines 59-67, Column 3, Lines 1-4).

Regarding Claim 17, arguments analogous to those presented for Claim 10 are applicable to Claim 17.

Regarding Claim 18, arguments analogous to those presented for Claims 1, 9, 10 and 12 are applicable to Claim 18.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mehrdad Dastouri whose telephone number is (703) 305-2438. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mehrdad Dastouri
Primary Examiner
Art Unit 2623
January 5, 2005

MEHRDAD DASTOURI
PRIMARY EXAMINER

Mehrdad Dastouri